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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,761	07/02/2003	Lishan Aklog	FLEX-001	7167

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BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

10/613.761

Applicant(s)

AKLOG. LISHAN

Examiner

Paul B. Prebilib

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2005.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.

4a) Of the above claim(s) 5, 14-16, 18, 19, 21-23, 25, 26, 29-44, 50, 54, and 58-62 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 21, 2005 has been entered.

Election/Restrictions

Claims 5, 14-16, 18, 19, 21-23, 25, 26, 29-44, 50, 54, and 58-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in paper filed in December 2004.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985), *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982), *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970), and, *In re Thorington*, 418 F.2d 528, 163 USPQ 844 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 27, 28, 45, and 63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 16, and 17 of copending Application No. 10/884,015. The present claims are read on by the copending claims such that the present claims are considered to be clearly obvious in view thereof. In other words, the present claims could be said to be "anticipated" or rendered clearly "obvious" by the subject matter set forth in the copending claims, and therefore, a double patenting rejection is deemed appropriate.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-13, 17, 20, 24, 27, 28, 45-49, 51-53, 55-56, and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, on line 5, in claim 45, on line 4 and claim 63, on line 4, the new limitation "extending inward thereof" is considered to be grammatically awkward is not understood by the Examiner because it is not clear what element the "extending inward thereof" is associated. The Examiner suggests changing "extending inward thereof" to --extending inwardly from the ring--- in order to overcome this rejection.

With regard to claim 1, line 7, the use of the term "inflow" is confusing because it appears that the restraining structure, as disclosed, is to keep the valve leaflets within the outflow side of the valve, not on the inflow side of the valve. The claims dependent upon claim 1 are also rejected because they contain the same indefinite language by incorporation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-12, 27, 45-49, 53, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Gabbay (WO 01/89418). Gabbay anticipates the claim language where the buttress (20) extends over at least a portion of the interior of the ring; see Figures 1, 4, 11, and 12 as well as page 5, line 14 et seq. At least a part of the restraining structure of Gabbay is within the plate defined by the ring. Furthermore, "generally" is a broad term and does not require the entire structure to be within the plane of the ring.

Claims 1-4, 9-13, 17, 20, 24, 27, 28, 45, 46, 51, 52, 57, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Bessler (WO 01/47438) where the restraining member as claimed is met by the template (206) of Bessler that reads on the claimed device', see Figures 9A and 9B as well as page 14.

Regarding claims 3, 6, 7, 8, 47, 48, and 49, the terms "elastic" and "non-elastic" are considered to be terms of relative degree such that the member of Bessler is considered to be elastic or flexible in certain stress regimes and rigid or inelastic in lower stress regimes.

Regarding claim 20, "substantially" is construed as being broad such that the arms of template (206) reads thereon.

With regard to claim 63, the term "permanent" is considered to be a term of intended use that does not preclude the template of Bessler in a structural sense.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al (WO 01/47438) or Gabbay (WO 01/89418) in view of Solem et al (US 6,210,432). Bessler or Gabbay meets the claim language but discloses that the device can be made of plastic or metal without specifying what types of metals or that titanium metals can be used. However, Solem teaches that it was known to make similar annuloplasty rings out of Nitinol, see column 3, lines 37-47. Nitinol is a type of nickel-titanium alloy. Therefore, it is the Examiner's position that it would have

been prima facie obvious to make the components of Bessler out of Nitinol for the same reasons that Solem does the same and because Nitinol is known to be a biocompatible and sufficiently strong material for heart valve repair as implicitly taught by Bessler.

Response to Arguments

Applicant's arguments filed April 14, 2005 have been fully considered but they are not persuasive.

In response to the argument that Gabbay does not have restraining structures within the plane of the ring, the Examiner asserts that the language is fully met by Gabbay because the claims do not require the restraining structure be entirely within the plane of the ring. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to the argument that Bessler's template is not an implantable device, the Examiner asserts that the claims are read on by Bessler due to the fact that all the structural limitations of the claims are met. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be

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applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738